ORIGINAL

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UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

B 1348

Patent Compliance Group, Inc.,

Relator,

v.

Wright Medical Technology, Inc.,

Defendant.

JURY TRIAL DEMANDED

Case No. _____

3-10CV0289-K

COMPLAINT FOR FALSE MARKING

Qui tam relator Patent Compliance Group, Inc. ("Patent Compliance Group"), for its Complaint against Defendant Wright Medical Technology, Inc. ("Defendant"), alleges, based on its own personal knowledge with respect to its own actions and based upon information and belief with respect to all others' actions, as follows:

BACKGROUND

1. This is an action for false patent marking under Title 35, Section 292, of the United States Code.

2. Defendant has violated 35 U.S.C. § 292(a) by marking unpatented articles with the purpose of deceiving the public. More specifically, Defendant has, with the purpose of deceiving the public:

(i) marked products with patents that have expired and, therefore, do not and cannot cover the marked products; and

(ii) used in advertising in connection with unpatented products the word "patent" and/or any word or number importing that the product is patented.

3. The marking and false marking statutes exist to give the public notice of patent rights. Congress intended the public to rely on marking as a ready means of discerning the status of intellectual property embodied in an article of manufacture or design. Federal patent policy recognizes an important public interest in permitting full and free competition in the use of ideas which are, in reality, a part of the public domain.

4. False patent marking – including representing through advertisement that a product is covered by a patent that has expired - is a serious problem. Acts of false marking deter innovation and stifle competition in the marketplace. If an article that is within the public domain is falsely marked, potential competitors may be dissuaded from entering the same market. False marks may also deter scientific research when an inventor sees a mark and decides to forego continued research to avoid possible infringement. False marking can cause unnecessary investment in design around or costs incurred to analyze the validity or enforceability of a patent whose number has been marked upon a product with which a competitor would like to compete. Furthermore, false marking misleads the public into believing that a patentee controls the article in question (as well as like articles), externalizes the risk of error in the determination, placing it on the public rather than the manufacturer or seller of the article, and increases the cost to the public of ascertaining whether a patentee in fact controls the intellectual property embodied in an article. In each instance where it is represented that an article is patented, a member of the public desiring to participate in the market for the marked article must incur the cost of determining whether the involved patents are valid and enforceable. Failure to take on the costs of a reasonably competent search for information necessary to interpret each patent, investigation into prior art and other information bearing on the quality of the patents, and analysis thereof can result in a finding of willful infringement, which may treble

the damages an infringer would otherwise have to pay. False markings may also create a misleading impression that the falsely marked product is technologically superior to previously available ones, as articles bearing the term "patent" may be presumed to be novel, useful, and innovative.

5. The false marking statute explicitly permits *qui tam* actions. By permitting members of the public to sue on behalf of the government, Congress allowed individuals to help control false marking.

6. Patent Compliance Group, on its own behalf and on behalf of the United States, seeks an award of monetary damages of not more than $500 for each of Defendant's violations of 35 U.S.C. § 292(a), one-half of which shall be paid to the United States pursuant to 35 U.S.C. § 292(b).

THE PARTIES

7. Patent Compliance Group is a Texas corporation with its principal place of business at 4223 Buena Vista Street, Suite 4, Dallas, Texas 75205.

8. Patent Compliance Group exists to conduct all lawful business, including but not limited to enforcing the false marking statute.

9. Patent Compliance Group represents the United States and the public, including Defendant's existing and future competitors.

10. Defendant is a Delaware corporation with its principal place of business at 5677 Airline Road, Arlington, Tennessee 38002.

11. Defendant regularly conducts and transacts business in Texas, throughout the United States, and within the Northern District of Texas, itself and/or through one or more subsidiaries, affiliates, business divisions, or business units. Defendant can be served with process through

any of its agents including officers or directors or its registered agent.

JURISDICTION AND VENUE

12. This Court has exclusive jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Defendant. Defendant has conducted and does conduct business within the State of Texas. Defendant, directly or through subsidiaries or intermediaries, offers for sale, sells, marks and/or advertises the products that are the subject of this Complaint in the United States, the State of Texas, and the Northern District of Texas.

14. Defendant has voluntarily sold the products that are the subject of this Complaint in this District, either directly to customers in this District or through intermediaries with the expectation that the products will be sold and distributed to customers in this District. These products have been and continue to be purchased and used by consumers in the Northern District of Texas. Defendant has committed acts of false marking within the State of Texas and, more particularly, within the Northern District of Texas.

15. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)-(c) and 1395(a), because (i) Defendant's products that are the subject matter of this cause of action are advertised, marked, offered for sale, and/or sold in various retail stores and/or on the Internet in this District; (ii) a substantial part of the events or omissions giving rise to the claim occurred in this District; and (iii) Defendant is subject to personal jurisdiction in this District, as described above.

16. Patent Compliance Group brings this action under 35 U.S.C. § 292(b), which provides that any person may sue for civil monetary penalties for false patent marking.

FACTS

17. Patent Compliance Group incorporates by reference the foregoing paragraphs as if

fully set forth herein.

18. Defendant is a large, sophisticated company with over 1000 employees.

19. Defendant has, or regularly retains, sophisticated legal counsel.

20. Defendant has decades of experience applying for patents, obtaining patents, and/or litigating in patent infringement lawsuits.

21. Each false marking on the products identified in this Complaint is likely to, or at least has the potential to, discourage or deter persons and companies from commercializing competing products.

22. Defendant's false marking of its products has wrongfully quelled competition with respect to such products thereby causing harm to Patent Compliance Group, the United States, and the public.

23. Defendant has wrongfully and illegally advertised patent monopolies which it does not possess and, as a result, has benefited by maintaining a substantial market share with respect to the products referenced in this Complaint.

24. Defendant knows that all patents expire and that all monopoly rights in the patent terminate irrevocably when it expires.

25. United States Patent No. 2,845,963 (the "'963 patent"), titled "*Dispensing Bottles*," was filed on April 16, 1956, was issued by the United States Patent and Trademark Office (the "USPTO") on August 5, 1958, and expired, at the latest, on August 5, 1975. (*See* Ex. A.)

26. United States Patent No. 4,298,992 (the "'992 patent"), titled "*Posteriorly Stabilized Total Knee Joint Prosthesis*," was filed on January 21, 1980, was issued by the USPTO on October 10, 1981, and expired, at the latest, on January 21, 2000. (*See* Ex. B.)

27. United States Patent No. 4,467,801 (the "'801 patent"), titled "*Method and*

Apparatus For Shaping A Proximal Tibial Surface," was filed on March 9, 1983, was issued by the USPTO on August 28, 1984, and expired at the latest, on March 9, 2003. (*See* Ex. C.)

28. United States Patent No. 4,474,177 (the "'177 patent"), titled "*Method and Apparatus For Shaping A Distal Femoral Surface*," was filed on March 9, 1983, was issued by the USPTO on October 2, 1984, and expired at the latest, on March 9, 2003. (*See* Ex. D.)

29. United States Patent No. 4,621,637 (the "'637 patent"), titled "*Surgical Device for Removing Bone and Tissue From Joint Members*," was filed on July 30, 1984, was issued by the USPTO on November 11, 1986, and expired at the latest, on July 30, 2004. (*See* Ex. E.)

30. United States Patent No. 4,718,413 (the "'413 patent"), titled "*Bone Cutting Guide and Methods for Using Same*," was filed on December 24, 1986, was issued by the USPTO on January 12, 1988, and expired at the latest, on December 24, 2006. (*See* Ex. F.)

31. United States Patent No. 4,851,008 (the "'008 patent"), titled "*Bone Implant Prosthesis With Substantially Stress-Free Outer Surface*," was filed on February 1, 1988, was issued by the USPTO on July 25, 1989, and expired at the latest, on February 1, 2008. (*See* Ex. G.)

32. United States Patent No. 4,865,871 (the "'871 patent"), titled "*Method for Cryopreparing Biological Tissue*," was filed on July 11, 1988, was issued by the USPTO on September 12, 1989, and expired at the latest, on July 11, 2008. (*See* Ex. H.)

33. United States Patent No. 4,935,023 (the "'023 patent"), titled "*Femoral Surface Shaping Guide for Knee Implants*," was filed on January 9, 1989, was issued by the USPTO on June 19, 1990, and expired at the latest, on January 9, 2009. (*See* Ex. I.)

34. United States Patent No. 4,936,860 (the "'860 patent"), titled "*Metal Scaphoid Implant*," was filed on September 23, 1988, was issued by the USPTO on June 26, 1990, and

expired at the latest, on September 23, 2008. (*See* Ex. J.)

35. United States Patent No. 4,955,915 (the "'915 patent"), titled "*Lunate Implant and Method of Stabilizing Same*," was filed on June 2, 1989, was issued by the USPTO on September 11, 1990, and expired at the latest, on June 2, 2009. (*See* Ex. K.)

36. United States Patent No. 4,957,510 (the "'510 patent"), titled "*Hip Prosthesis Structure Adapted for Easy Fitting to the Patient Coxo-Femural Articulation*," was filed on July 26, 1988, was issued by the USPTO on September 18, 1990, and expired at the latest, on July 26, 2008. (*See* Ex. L.)

37. United States Patent No. 4,198,713 (the "'713 patent"), titled "*Protective Member for Implantable Prosthesis and Method of Protecting the Prosthesis*," was filed on March 29, 1979, was issued by the USPTO on April 22, 1980, and expired at the latest, on March 29, 1999. (*See* Ex. M.)

38. United States Patent No. 4,219,893 (the "'893 patent"), titled "*Prosthetic Knee Joint*," was filed on September 1, 1977, was issued by the USPTO on September 2, 1980, and expired at the latest, on September 2, 1997. (*See* Ex. N.)

39. United States Patent No. 4,262,368 (the "'368 patent"), titled "*Rotating and Hinged Knee Prosthesis*," was filed on September 24, 1979, was issued by the USPTO on April 21, 1981, and expired at the latest, on September 24, 1999. (*See* Ex. O.)

40. United States Patent No. 4,301,553 (the "'553 patent"), titled "*Prosthetic Knee Joint*," was filed on May 23, 1980, was issued by the USPTO on November 24, 1981, and expired at the latest, on May 23, 2000. (*See* Ex. P.)

41. United States Patent No. 4,808,185 (the "'185 patent"), titled "*Tibial Prosthesis, Template and Reamer*," was filed on February 7, 1986, was issued by the USPTO on February

28, 1989, and expired at the latest, on February 28, 2006. (*See* Ex. Q.)

42. United States Patent No. 4,721,104 (the "'104 patent"), titled "*Femoral Surface Shaping Apparatus for Posterior-Stabilized Knee Implants*," was filed on December 2, 1985, was issued by the USPTO on January 26, 1988, and expired at the latest, on December 2, 2005. (*See* Ex. R.)

43. United States Patent No. 4,722,330 (the "'330 patent"), titled "*Femoral Surface Shaping Guide for Knee Implants*," was filed on April 26, 1986, was issued by the USPTO on February 2, 1988, and expired at the latest, on April 26, 2006. (*See* Ex. S.)

44. United States Patent No. 4,759,767 (the "'767 patent"), titled "*Prosthesis for Tibial Component of Knee Joint*," was filed on August 10, 1987, was issued by the USPTO on July 26, 1988, and expired at the latest, on August 10, 2007. (*See* Ex. T.)

45. Because the '963, '992, '801, '177, '637, '413, '008, '871, '023, '860, '915, '510, '713, 893, 368, '553, '185, '104, '330, and '767 patents (collectively the "Expired Patents") are expired, any product or method once covered by the claims of the Expired Patents is no longer protected by the patent laws of the United States. When the Expired Patents expired, their formerly protected property entered the public domain.

46. Despite the fact that the claims of the Expired Patents are no longer afforded patent protection, Defendant has and continues to mark (or causes to be marked) various products with one or more of the Expired Patents.

47. Despite the fact that the claims of the Expired Patents are no longer afforded patent protection, Defendant has and continues to advertise on its website and product materials that various products are covered by one or more of the Expired Patents.

48. Defendant marks and advertises the Cellplex® product line as being covered by the

expired '963 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U.)[1]

49. Defendant marks and advertises the Advance® and Conserve® products lines as being covered by the expired '992 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U, V and W.)

50. Defendant marks and advertises the Axiom® product line as being covered by the expired '801 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U and X.)

51. Defendant marks and advertises the Advantim® product line as being covered by the expired '177 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U and X.)

52. Defendant marks and advertises the Con-Nex® product line as being covered by the expired '637 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U.)

53. Defendant marks and advertises the Axiom®, Advance® and Conserve® product lines as being covered by the expired '413 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U, V and W.)

54. Defendant marks and advertises the Axiom® product line as being covered by the expired '008 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U.)

55. Defendant marks and advertises the GraftJacket® product line as being covered by the

[1] To avoid unnecessarily burdening the Court with voluminous exhibits, Patent Compliance Group attaches a representative sampling of Defendant's product materials and advertisements containing references to the Expired Patents to this Complaint.

expired '871 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U, Y and Z.)

56. Defendant marks and advertises the Advantim® product line as being covered by the expired '023 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U and X.)

57. Defendant marks and advertises the Orthosphere® and Swanson Titanium Carpal Scaphoid Implant product lines as being covered by the expired '860 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U, AA and BB.)

58. Defendant marks and advertises the Orthosphere® and Swanson Titanium Carpal Lunate Implant product lines as being covered by the expired '915 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U, AA and BB.)

59. Defendant marks and advertises the Profemur® and Lineage® product lines as being covered by the expired '510 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, U, CC and DD.)

60. Defendant marks and advertises the Orthosphere® product line as being covered by the expired '713 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, AA and BB.)

61. Defendant marks and advertises The Total Knee System product line as being covered by the expired '893 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, X.)

62. Defendant marks and advertises The Total Knee System product line as being

covered by the expired '368 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, X.)

63. Defendant marks and advertises The Total Knee System product line as being covered by the expired '553 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, X.)

64. Defendant marks and advertises The Total Knee System product line as being covered by the expired '185 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, X.)

65. Defendant marks and advertises The Total Knee System product line as being covered by the expired '104 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, X.)

66. Defendant marks and advertises The Total Knee System product line as being covered by the expired '330 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, X.)

67. Defendant marks and advertises The Total Knee System product line as being covered by the expired '767 patent. Examples of Defendant's false marking and false advertising include product materials published on its website. (*See, e.g.*, X.)

68. Defendant's products and product lines referenced above shall be collectively referred to as the "Patent Expired Products."

69. Defendant knows that the Expired Patents do not cover the Patent Expired Products.

70. Alternatively, because all monopoly rights in the Expired Patents have terminated, Defendant cannot have any reasonable belief that the Patent Expired Products are covered by one or more of the Expired Patents.

71. Despite its knowledge of patent law and the current status of the Expired Patents, Defendant has and continues to falsely mark (or causes to be marked) and falsely advertise the Patent Expired Products as being covered by one or more of the Expired Patents.

72. Defendant intended to and has deceived the public by falsely marking (or causing to be marked) and falsely advertising the patent protection status of the Patent Expired Products.

COUNT I
(False Marking With Expired Patents)

73. Patent Compliance Group incorporates the foregoing paragraphs by reference as if fully set forth herein.

74. Defendant falsely marked the Patent Expired Products as being covered by and subject to one or more of the Expired Patents.

75. Defendant knew or reasonably should have known that marking the Patent Expired Products with one or more of the Expired Patents is in violation of 35 U.S.C. § 292, which only authorizes marking on a "patented" article.

76. Defendant intended to deceive the public by marking the Patent Expired Products with one or more of the Expired Patents.

55. Defendant's actions are in violation of 35 U.S.C. § 292.

COUNT II
(False Advertising Under the False Marking Statute)

56. Patent Compliance Group incorporates the foregoing paragraphs by reference as if fully set forth herein.

57. Defendant falsely advertised the Patent Expired Products as being covered by and subject to one or more of the Expired Patents.

58. Defendant knew or reasonably should have known that the Patent Expired Products are not covered by and are no longer subject to one or more of the Expired Patents.

59. Defendant intended to deceive the public by advertising that the Patent Expired Products are covered by and subject to one or more of the Expired Patents.

60. Defendant's actions are in violation of 35 U.S.C. § 292.

PRAYER FOR RELIEF

Patent Compliance Group requests the Court, pursuant to 35 U.S.C. § 292, to:

A. Enter judgment against Defendant and in favor of Patent Compliance Group for the violations alleged in this Complaint;

B. Enter an injunction prohibiting Defendant, and its officers, directors, agents, servants, employees, attorneys, licensees, successors, and assigns, and those in active concert or participation with any of them, from violating 35 U.S.C. § 292;

C. Order Defendant to pay a civil monetary fine of up to $500 per false marking "offense," one-half of which shall be paid to the United States and one-half of which shall be paid to Patent Compliance Group;

D. Enter a judgment and order requiring each Defendant to pay Patent Compliance Group prejudgment and post-judgment interest on the damages awarded;

E. Order Defendant to pay Patent Compliance Group's costs and attorney fees; and

F. Grant Patent Compliance Group such other and further relief as it may deem just and equitable.

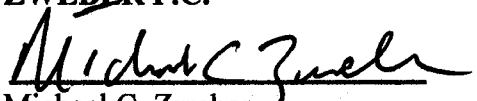
JURY DEMAND

Patent Compliance Group, pursuant to Federal Rule of Civil Procedure 38(b), hereby demands a trial by jury on all issues so triable.

Dated: February 12, 2010

Respectfully submitted,

ZWEBER P.C.

By: 

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ATTORNEY FOR RELATOR
PATENT COMPLIANCE GROUP, INC.

Exhibit A

United States Patent Office 2,845,963 Patented Aug. 5, 1958

2,845,963

DISPENSING BOTTLES

Eli A. Zackheim, South Plainfield, N. J., assignor to Johnson & Johnson, a corporation of New Jersey

Application April 16, 1956, Serial No. 578,297

14 Claims. (Cl. 141—24)

This invention relates to improvements in dispensing bottles.

The general object of the invention is to provide a dispensing bottle equipped with, or usable with, a dropper in which loss due to spillage, when the bottle is accidentally overturned, is minimized, as also danger of drinking of the contents by small children.

A dispensing bottle embodying the invention in a preferred form will now first be described with reference to the accompanying drawing and the features forming the invention will then be pointed out in the appended claims.

In the drawing:

Fig. 1 is a central or axial section of a bottle embodying the invention in a preferred form;

Fig. 2 is a view similar to Fig. 1, but with a stopper and dropper element removed;

Fig. 3 is a view similar to Fig. 2, but showing the bottle inverted;

Fig. 4 is an enlarged fragmentary elevational view of a part of Fig. 1;

Fig. 5 is a view similar to Fig. 1, but showing a modification; and

Fig. 6 is a bottom elevational view of the bottle of Fig. 5.

The bottle 10 of Fig. 1 may be of glass and otherwise of usual construction and shape. Fitted in the neck and in sealing relation thereto is a well tube 11 which may have a narrowed tip 12 and enlarged upper end 13, the upper end 13 fitting in the bottle neck, as indicated. The well tube 11 is conveniently made of polyethylene or other somewhat resilient material, at least as to the upper end 13, so that the upper end forms a plug or stopper effectively sealing to the bottle neck by pressure contact along the engaging or abutting surface 14. The tip 11 may have a flange 16 to limit its downward or inward movement and seating on the top of the bottle 10, as indicated.

Fitting comfortably within the tube 11 is a barrel or body portion 17 of the dropper and cap assembly 18, which body portion may be of glass, polyethylene or any other suitable material. The uper end of the dropper assembly 18 comprises an elastic bulb 19 secured to a bottle cap element 20, which may be a screw cap, as shown, being internally threaded to fit the usual thread 21 molded in the bottle neck. The bulb 19 may be of rubber and the cap 20 of suitable comparatively rigid material, these two elements being assembled together by molding a groove 22 in the bulb within which the top of the cap 20 surrounding a simple aperture 23 is accommodated, the bulb 19 having sufficient elasticity to permit snapping the parts together. The dropper barrel 17 is formed with an outwardly extending rim or flange 25 received within an internal groove 26 of the bulb 19, the bulb element 19 below the groove fitting the barrel 17 at 27, as indicated. As will be understood, the material of the bulb element 19 is sufficiently elastic to permit insertion of the barrel 17 through the opening at 27.

The groove 26 is preferably elongated in the axial direction, as shown, and fits the rim or flange of the barrel 17. In the initial assembly, the dropper element 18 is assembled together with the bottle 10, with the rim 25 in a downward position in the groove 26, so that when the tip 28 of the barrel 17 engages the bottom of the bottle, further screwing on of the cap 20 will locate the rim 25 at the proper position along the groove 26 for positioning the barrel tip 28 in contact with the bottom of the bottle when the cap is screwed on the bottle. In this way, the tip of each dropper may be brought to the bottom of the bottle, despite variation in the vertical dimensions of normally available bottles. To permit liquid access, the tip 28 is notched as indicated at 29.

When the bottle is full or substantially so, the level 30 around the well tube 11 may be about as indicated in Fig. 1, while the level 31 within the well tube 11 may be much lower and may also be about as indicated. Since any rise in the level 31 involves a drop in the level 30 and a corresponding increase in volume in the trapped air space above this level within the bottle 10 and around the well tube 11, the well tube 11 may be practically empty while the bottle around the well tube is practically full.

The removal of the stopper or dropper element 18, as indicated in Fig. 2, does not essentially change conditions, the liquid levels remaining about the same. If now the bottle is inverted, as indicated in Fig. 3, a small amount of liquid within the well tube 11 will be discharged, plus such small amount as may enter this tube during the tipping movement. However, once the bottle is inverted, the liquid level 30′ (Fig. 3) will now be below the open end of the tube 11, so that there would be no further escape of the contents. As will be apparent, loss of liquid due to tipping as well as danger of drinking an excess and dangerous dose by children or others from the bottle is minimized.

In the modified construction shown in Figs. 5 and 6, a bottle 40 having a rounded inside bottom 41 is utilized to permit even more complete dispensing by means of the dropper of the contents. In this case, well tube 42 goes to the bottom of the bottle and is notched as at 43 to permit flow of liquid, from the space outside the well tube into its interior. The tube 42 has a pressure fit forming a sealing engagement with the inside of the bottle neck along the surface 44. In this case, the upper end of the well tube 42 may serve to determine the depth to which the tube of the dropper barrel 45 goes within the bottle. The dropper is shown as of a conical shape, terminating as before in an upper flange 46 which snaps into a groove formed in the inner wall of the resilient bulb element 47. The latter has a snug fit within the cap 48 engaging the inner wall 49 of the top aperture therein, and is held in position vertically with respect to the cap by means of a lower flange 50, as indicated. The cap and bottle are correspondingly threaded, as before.

What is claimed is:

1. A dispensing liquid container comprising, in combination, a bottle having a neck opening, a well tube fitting in the neck opening in sealed relation thereto and extending downwardly to a point adjacent the bottom of the bottle so as to separate the interior of the bottle generally into a space within the well tube and a space outside it, a cap fitting the bottle in sealing relation thereto and comprising a dropper having a barrel accommodated within the well tube, the tip of the dropper barrel being also adjacent the bottom of the bottle when the cap is in position on the bottle.

2. A dispensing liquid container comprising, in combination, a bottle having a neck opening, a well tube fitting in the neck opening in sealed relation thereto and

extending downwardly to a point adjacent the bottom of the bottle so as to separate the interior of the bottle generally into a space within the well tube and a space outside it, a cap fitting the bottle in sealing relation thereto and comprising a dropper having a barrel accommodated within the well tube, the tip of the dropper barrel extending closer to the bottom of the bottle than the well tube when the cap is in position on the bottle.

3. A dispensing liquid container comprising, in combination, a bottle having a neck opening, a well tube fitting in the neck opening in sealed relation thereto and extending downwardly to a point adjacent the bottom of the bottle so as to separate the interior of the bottle generally into a space within the well tube and a space outside it, while leaving space for flow between said spaces below a predetermined level, a cap fitting the bottle in sealing relation thereto and comprising a dropper having a barrel accommodated within the well tube, the tip of the dropper barrel being below the said level when the cap is in position on the bottle.

4. A dispensing liquid container according to claim 3, in which the bottom of the well tube has a configuration different from the bottom of the bottle, whereby the well tube may abut against the bottom of the bottle while leaving said space for flow.

5. A dispensing liquid container according to claim 3, in which the lower end of the well tube is notched so as to provide said space for flow.

6. A dispensing liquid container according to claim 3, in which the tip of the dropper barrel is notched to permit flow into the dropper barrel when it is in contact with the bottom of the bottle.

7. A dispensing liquid container comprising, in combination, a bottle having a neck opening, a well tube fitting in the neck opening in sealed relation thereto and extending downwardly to a point adjacent the bottom of the bottle so as to separate the interior of the bottle generally into a space within the well tube and a space outside it, a dropper having a barrel accommodated within the well tube and abutment means engaging the neck of the bottle to limit the insertion of the dropper, the tip of the dropper barrel being also adjacent the bottom of the bottle when the abutment means is in engagement with the bottle neck.

8. A dispensing liquid container comprising, in combination, a bottle having a neck opening and having a concave bottom, a well tube fitting in the neck opening in sealed relation thereto and extending downwardly to a point adjacent the deepest part of the bottom of the bottle so as to separate the interior of the bottle generally into a space within the well tube and a space outside it, a cap fitting the bottle and comprising a dropper having a barrel accommodated within the well tube, the tip of the dropper barrel being also adjacent the bottom of the bottle when the cap is in position on the bottle.

9. A dispensing liquid container comprising, in combination, a bottle having a neck opening, a well tube fitting in the neck opening in sealed relation thereto and extending downwardly to a point adjacent the bottom of the bottle so as to separate the interior of the bottle generally into a space within the well tube and a space outside it, while leaving space for flow between said spaces below a predetermined level, a cap fitting the bottle and comprising a dropper having a barrel accommodated within the well tube, the dropper comprising a bulb and barrel holding elements receiving and frictionally holding the upper end of the barrel, whereby the barrel position in the bottle may be adjusted to bring its tip in contact with the bottom of the bottle when the cap is in position thereon.

10. A dispensing liquid container according to claim 9, in which the tip of the dropper barrel has a configuration different from the bottom of the bottle, whereby the said tip may abut against the bottom of the bottle while leaving space for flow into the barrel.

11. A dispensing liquid container according to claim 9, in which the tip of the dropper barrel is notched to permit flow into the dropper barrel when it is in contact with the bottom of the bottle.

12. A dispensing liquid container according to claim 9, in which the barrel holding element has an internal groove and the barrel has an upper flange frictionally fitting therein and slidable axially thereof.

13. A dispensing liquid container comprising, in combination, a bottle having a neck opening, a cap fitting the bottle and comprising a dropper having a barrel extending within the bottle, the dropper comprising a bulb and means for holding the barrel in operative relation thereto, the last said means comprising a member having an internal groove and a flange on the barrel frictionally fitting therein and slidably axially thereof, whereby the barrel position in the bottle may be adjusted to bring its tip in predetermined relation to the bottom of the bottle when the cap is in position thereon.

14. A dispening liquid container according to claim 13, in which the barrel length from tip to flange exceeds the distance from the bottom of the bottle to the said groove, whereby placing the cap in position on the bottle will force the barrel upwardly so as to locate the said flange in the groove at the proper position for bringing the tip of the barrel into contact with the bottom of the bottle.

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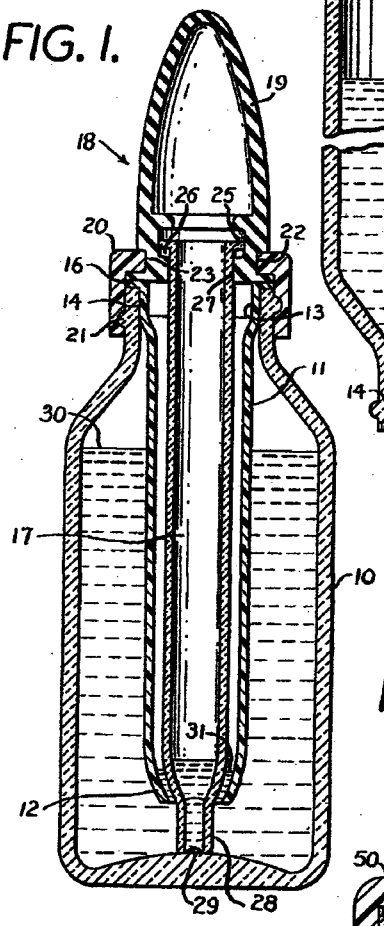
Aug. 5, 1958 E. A. ZACKHEIM 2,845,963

DISPENSING BOTTLES

Filed April 16, 1956

FIG. 1.



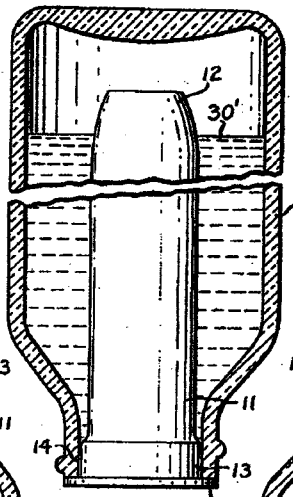


FIG. 3.

FIG. 2.

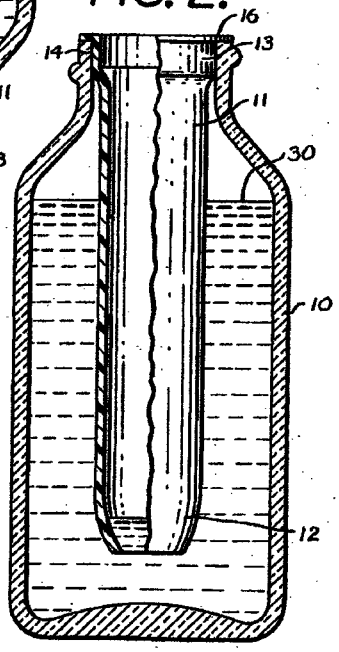


FIG. 5.

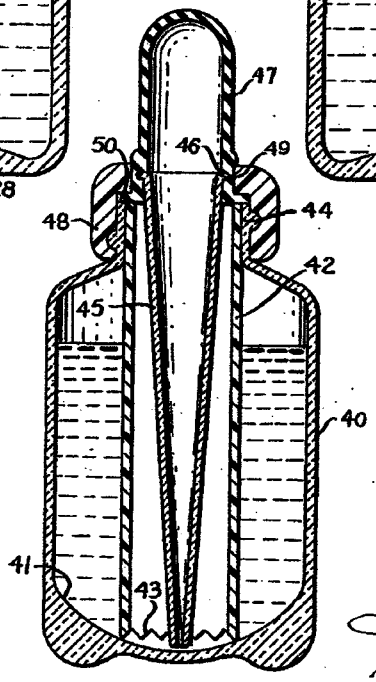


FIG. 6.

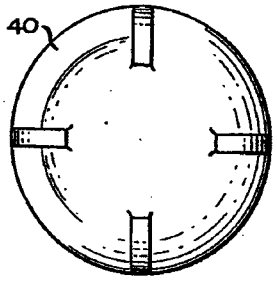
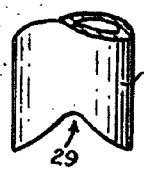


FIG. 4.



INVENTOR
ELI A. ZACKHEIM.

BY

ATTORNEY

Exhibit B

United States Patent [19]

Burstein et al.

[11] **4,298,992**

[45] **Nov. 10, 1981**

[54] **POSTERIORLY STABILIZED TOTAL KNEE JOINT PROSTHESIS**

[75] Inventors: **Albert H. Burstein**, Greenwich, Conn.; **John N. Insall**, Scarsdale, N.Y.

[73] Assignee: **New York Society for the Relief of the Ruptured and Crippled**, New York, N.Y.

[21] Appl. No.: **113,632**

[22] Filed: **Jan. 21, 1980**

[51] **Int. Cl.**[3] **A61F 1/03**

[52] **U.S. Cl.** ..... **3/1.911**; 128/92 C

[58] **Field of Search** ..... 3/1.911; 128/92 C

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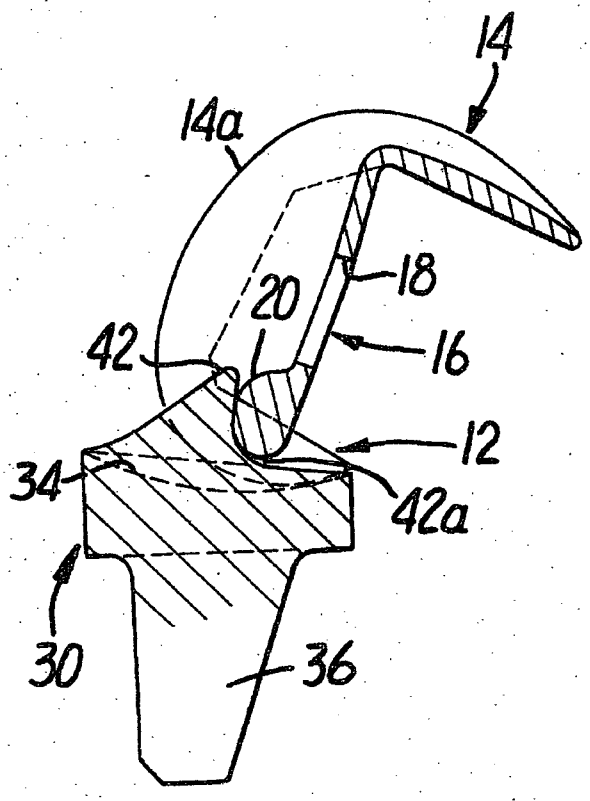
Primary Examiner—Clifford D. Crowder
Attorney, Agent, or Firm—Brumbaugh, Graves, Donohue & Raymond

[57] **ABSTRACT**

A box-like recess between the condylar portions of the femoral component has a transverse convexly curved cam follower portion at the posterior extremity of a superior wall which engages a concave cam surface at the inferior portion of the posterior surface of a tibial post that extends up from the plateau surface of the tibial component into the recess. The camming action between the cam follower and cam surface forces the zones of contact between the condylar portions of the femoral component and concavities in the tibial component posteriorly as the leg approaches full flexion, thereby increasing the range of flexion without interference between posterior surfaces of the femur and the tibial component and preventing anterior dislocation of the femur. The plateau of the tibial component slopes inferiorly and posteriorly, also to increase the range of flexion without interference.

4 Claims, 12 Drawing Figures



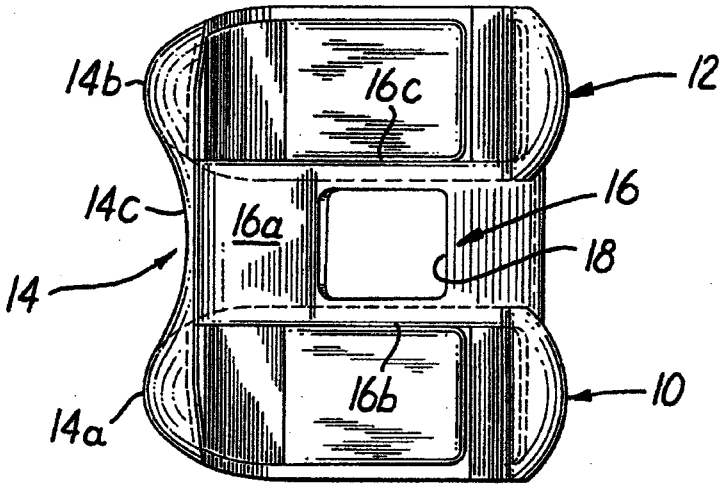


FIG. 1

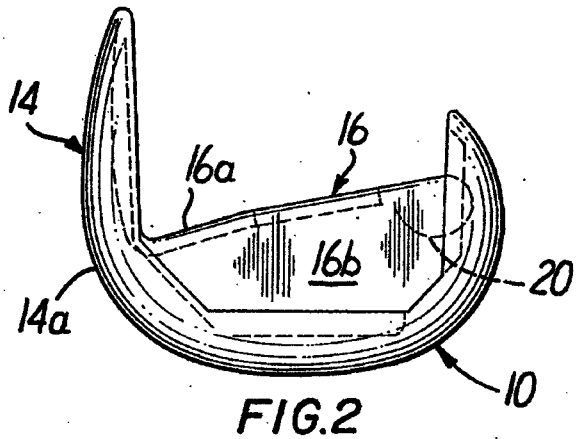


FIG. 2

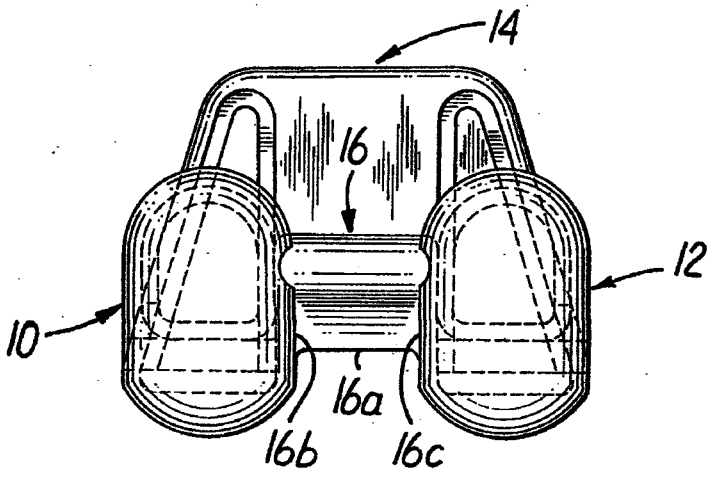


FIG. 3

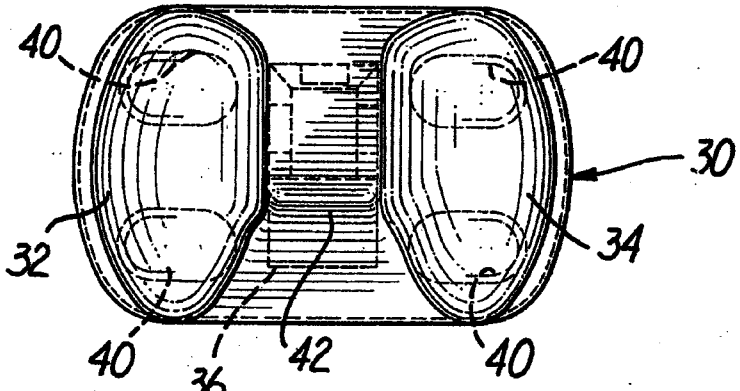


FIG. 4

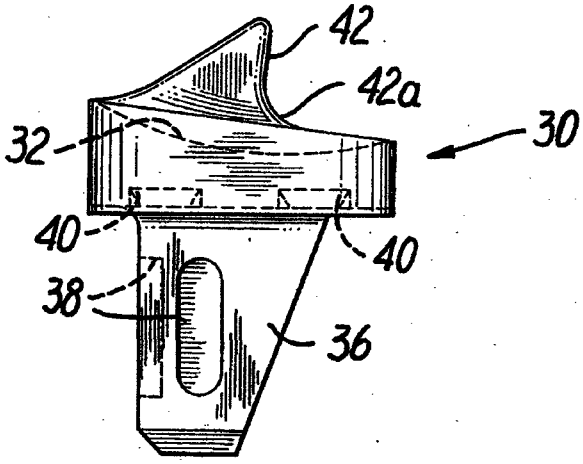


FIG. 5

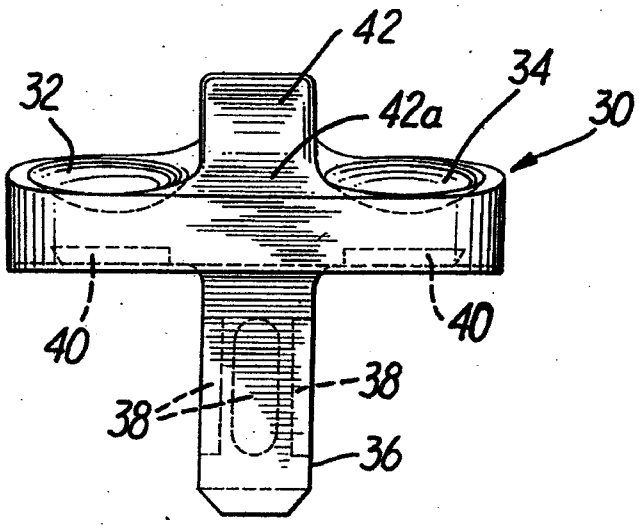


FIG. 6

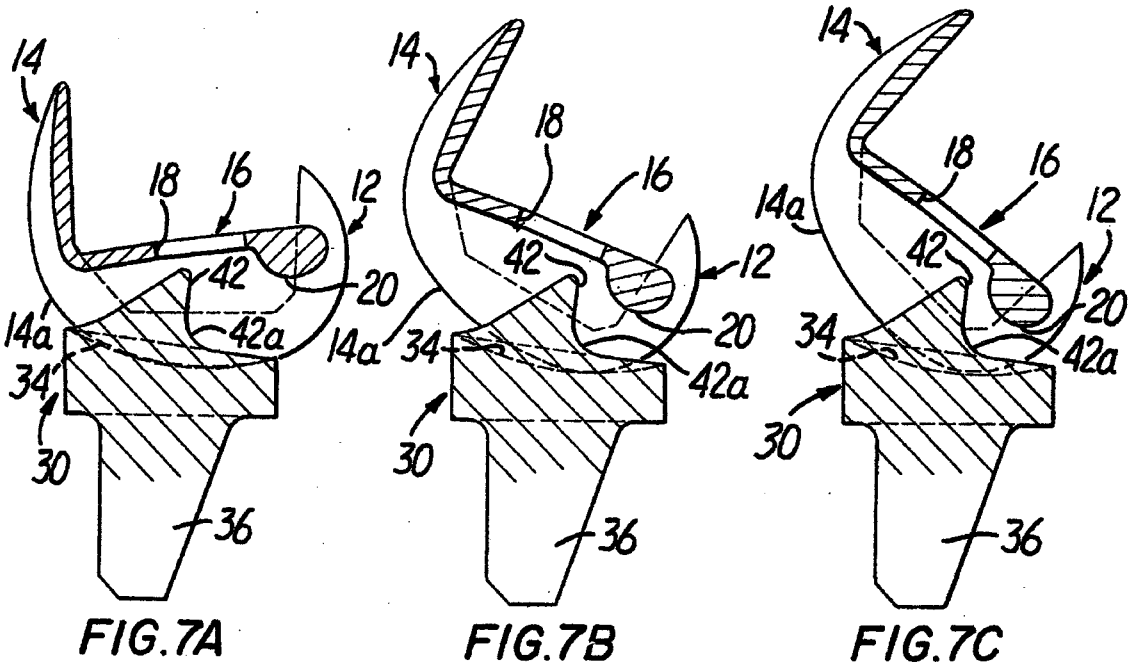


FIG.7A FIG.7B FIG.7C

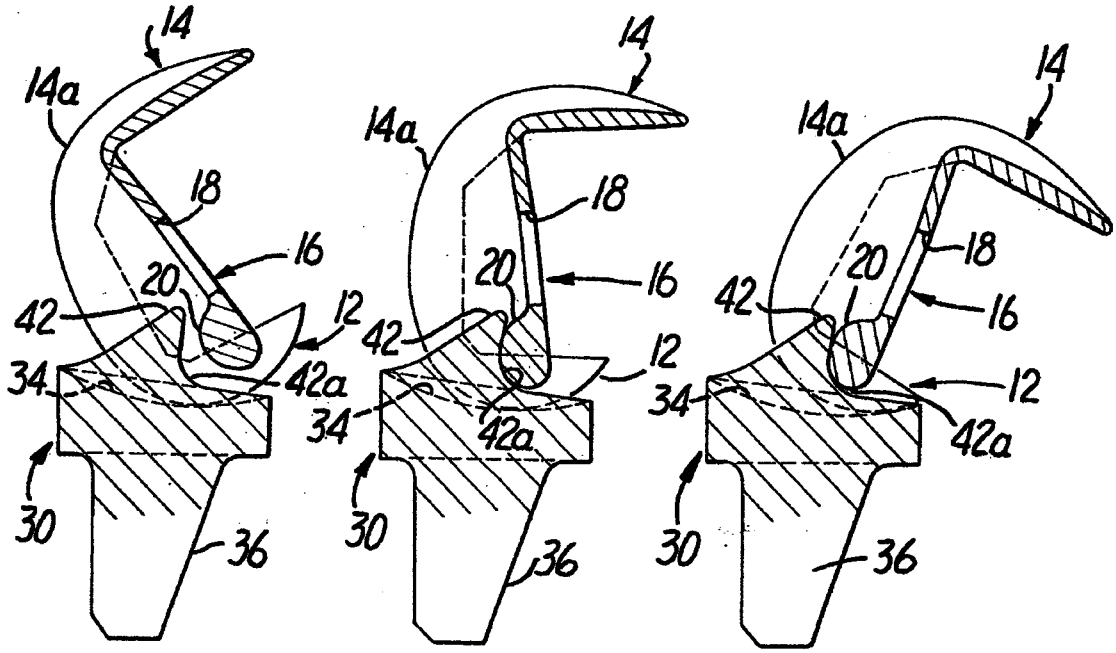


FIG.7D FIG.7E FIG.7F

POSTERIORLY STABILIZED TOTAL KNEE JOINT PROSTHESIS

FIELD OF THE INVENTION

The present invention relates to knee joint prostheses and, in particular, to an implantable knee joint prosthesis which replaces all surfaces of the femur and tibia which engage each other at the knee joint and stabilizes joint function in leg flexion.

BACKGROUND OF THE INVENTION

Researchers at the Hospital for Special Surgery, New York, N.Y. (the assignee of the present invention) have been working for many years on the development of prosthetic joints, including the knee joint. Developments in prosthetic knee joints have come to focus on "total" prostheses in which all contacting surfaces of the femur and tibia are replaced by surfaces of the femoral and tibial components of the prosthesis and on "stabilized" prostheses in which parts of the components, such as hinge pins or balls and sockets, control the motion. In general, the total knee prostheses currently used allow antero-posterior translation, lateral angulation and rotation in much the same way as the anatomical knee joint does and rely on the tendons and ligaments to impart stability. In some cases, however, the soft tissue is inadequate for one reason or another to provide the required stability, and the prosthesis is highly subject to dislocation and therefore of impaired usefulness in restoring normal function.

Hinge and ball and socket type knee joint prostheses generally fail to reproduce the motions of the anatomical joint. For that reason, they are not considered desirable, except for patients having inadequate soft tissue in the knee joint to provide stability, because normal function is not restored—the joint functions abnormally. Moreover, reliance on the mechanics of the prosthesis for stability places considerable strain on the prosthesis, and failure by dislodgment of the components is much much more prevalent with stabilized prostheses than with total prostheses.

U.S. Pat. No. 4,213,209 issued July 22, 1980 for "KNEE JOINT PROSTHESIS" (owned by the assignee of the present invention), describes and shows a knee joint prosthesis which can be characterized as a hybrid of the total and stabilized types. It has the attribute of providing generally normal function characteristic of total prostheses and the attribute of limiting certain excessive relative motions characteristic of stabilized prostheses.

SUMMARY OF THE INVENTION

The present invention provides certain improvements in the knee joint prostheses of U.S. Pat. No. 4,213,209 (referred to above). The prosthesis, according to the present invention, shares several features and principles with the one to which that application is directed. Thus, it comprises a femoral component having a pair of laterally spaced-apart condylar portions, each of which has an external surface that is smoothly convexly curved antero-posteriorly to match generally the lateral profile of the anatomical femoral condyle and smoothly convexly curved lateraly throughout its antero-posterior extent. A box-like structure connects the condylar portions and defines an intercondylar recess which opens inferiorly toward the tibia. The tibial component has a platform portion having laterally spaced-apart concavities, each of which receives one of the condylar portions of the femoral component. A post extends superiorly from the tibial plateau into the intercondylar recess of the femoral component. To the extent described thus far, the present invention allows relative motions (antero-posterior translation, lateral angulation and rotation) closely resembling those of the anatomical joint and some total prosthetic joints and limits excessive motions by engagement between the tibial post and femoral recess. Those features it shares with the prosthesis of U.S. Pat. No. 4,213,209.

The principal improvements of the present invention are:

(1) a transverse, convex cam follower portion at the posterior extremity of the superior wall of the femoral intercondylar recess engages a concave cam surface at the inferior, posterior portion of the tibial post at and near full flexion and forces the zones of contact between the femoral condylar portions and the tibial concavities posteriorly as flexion approaches full;

(2) the tibial plateau slopes inferiorly and posteriorly;

(3) the superior wall of the femoral recess is generally flat and slopes only slightly antero-inferiorly, relative to a nominal base plane, and does not engage the tibial post except under a relatively high amount (say, 15 degrees) of hyper-extension.

The modifications alter several aspects of the function of the prosthesis and provide several advantages. Among the more important are the following:

(1) the camming action between the tibial post and the femoral intercondylar recess that occurs near and at full flexion occurs at a region close to the tibial plateau-leverage tending to cause dislodgment of the tibial component is minimized.

(2) The camming action near and at full flexion makes the femoral component "ride" posteriorly on the tibial component, thereby increasing the range of flexion without interference between posterior surfaces of the femoral condyle and the posterior extremity of the tibial component.

(3) The postero-inferior slope of the tibial plateau likewise increases the range of flexion by lowering the posterior extremity of the tibial plateau while still retaining height at the anterior extremity for good "nesting" of the femoral condyles in the tibial concavities at extension and the consequential stabilizing effect of nesting at extension, especially stability against anterior displacement of the femur.

(4) Generally, the knee joint (both an anatomical and a prosthetic) is inherently stable at extension when the patient is standing—the nesting of the femoral condyles on the tibial plateau, the weight of the body generally centered over the knees and the status of the ligaments and tendons are all favorable to knee joint stability. It is, therefore, generally superfluous for the prosthetic joint to provide extra stability by engagement between the tibial post and femoral intercondylar recess at extension.

(5) The generally horizontal superior wall (roof) of the femoral intercondylar recess facilitates implantation of the tibial component by allowing plenty of room for the surgeon to insert the tibial component between the then implanted femoral component and the exposed tibia and then push it down into place.

(6) Under hyper-extension joint stability is diminished—the invention provides stability against posterior dislocation of the femur under hyper-extension by en-

gagement between the anterior wall of the post and the anterior portion of the roof of the recess.

For a better understanding of the invention reference may be made to the following description of an exemplary embodiment, taken in conjunction with the figures of the accompanying drawings.

DESCRIPTION OF THE DRAWINGS

FIGS. **1**, **2** and **3**, are plan, side elevational, and rear elevational views, respectively, of the femoral component;

FIGS. **4**, **5** and **6** are plan, side elevational and rear elevational views of the tibial component; and

FIGS. **7A** to **7F** are side cross-sectional views in generally schematic form showing the assembled components in various positions (corresponding to a range of leg articulation from full extension to full flexion).

DESCRIPTION OF THE EMBODIMENT

The femoral component comprises a pair of identical laterally spaced-apart femoral condylar portions **10** and **12**, each of which is smoothly convexly curved in lateral profile generally to match the curvature of an anatomical femoral condyle and is laterally convexly curved entirely along its antero-posterior extent. The anterior parts of the condylar portions merge smoothly with convexly curved lateral portions **14***a* and **14***b* of a patellar portion **14**, the medial part **14***c* of which is laterally concave and inferosuperiorly convex and intersects at its inferior extremity a superior wall or roof **16***a* of a box-like intercondylar portion **16** which, together with patellar portion **14**, connects the condylar portions. A pair of laterally spaced-apart side walls **16***b* and **16***c* of the recess join the edges of the roof **16***a* to the internal edges of the condylar portions. A hole **18** in the roof of the intercondylar portion **16** allows fluids and tissue more readily to enter and grow into the recess defined by the intercondylar recess for better intergration of the component with anatomical structures and systems.

The surfaces of the femoral component which face the femur are generally flat and, in the case of the "facets" of each condylar portion **10** and **12**, are bounded by a small rib or flange, thus to provide a keying effect which holds the component securely on the cement used to attach the component to the femur.

The roof **16***a* of the intercondylar recess **16** is generally flat (though it does have a slight break between two flat surfaces) and, though generally horizontal (parallel to a nominal base plane), slopes postero-superiorly toward a transverse, convex cam follower surface **20** at the posterior extremity. The notches on the internal edges of the posterior parts of the condylar portions (FIG. **3**) are there for a purpose relating to the surgical technique and do not have anything to do with the anatomical structure or function of the prosthesis. The femoral component is preferably made of a surgical grade, durable metal, such as a 316L stainless steel or a chrome-cobalt-molybdenum alloy meeting ASTM Standard #F75-74. All surfaces which are external to the bone are highly polished. The femoral component is symmetrical about a vertical antero-posterior center plane, so it can be used on either knee.

The tibial component (FIGS. **4** to **6**) is preferably made of a surgical grade, low-friction, high density, low wearing plastic, such as RCH-1000, and is also symmetrical about a vertical antero-posterior center plane for right or left use. It comprises an oblong, rounded, disc-like plateau portion **30**, the upper surface of which is generally flat and slopes down from front to back. Each of a pair of laterally spaced-apart, oblong concavities **32** and **34** receives one of the femoral condylar portions; the "nested" support of the femoral component stabilizes the prosthetic joint but still permits antero-posterior translation, lateral angulation and rotation, all of which are involved in normal function of the anatomical knee joint. The lateral curvature is slightly greater than the lateral curvature of the femoral condylar portions.

A keel-like fixation post **36** extends from the inferior surface of the plateau portion. Cement intrudes into slots **38** in the walls of the fixation post and slots **40** on the inferior surface of the plateau portion and anchors the tibial component to the cement.

A stabilizing post **42** extends superiorly from the plateau portion between the concavities and is received in the femoral intercondylar recess **16**. The post **42** is generally triangular in lateral profile and has flat, parallel lateral surfaces, a concave cam surface **42***a* at the inferior part of the posterior surface, and an anterior surface which slopes anteriorly and superiorly at an acute included angle to a nominal reference plane perpendicular to the nominal axis of the extended leg. The lateral surfaces of the stabilizing post **42** are in sufficient clearance from the lateral walls of the femoral intercondylar recess to allow normal lateral angulation and rotation of the prosthetic knee joint.

With the leg extended (FIG. **7A**) a generally stable position is established by nesting of the femoral condyles in the tibial plateau concavities; the tibial stabilizing post **42** and femoral recess **16** do not engage in the antero-posterioral direction. Under moderate degrees of flexion (FIGS. **7B** and **7D**) the post and recess continue to remain functionally dormant, but as flexion increases, the greater is the tendency for the femoral cam follower **20** to engage the posterior surface of the tibial post **42**, should the hamstring muscles of the thigh pull the tibia backward and tend to dislocate it posteriorly. Somewhere around 40° to 50° flexion (FIG. **7E**) the femoral cam follower **20** should ordinarily engage the tibial cam surface **42***a* and as flexion increases beyond that point will force the prosthetic femoral condyles to roll back in the tibial concavities (FIG. **7F**) observe that the zone of contact between the condyles and the concavities shifts posteriorly (compare FIGS. **7E** and **7F**) to a location very close to the posterior extremity of the tibial plateau at full flexion. This shift and the sloping of the tibial plateau allows a high flexion to occur without interference between the posterior extremity of the femur and the posterior extremity of the tibial component. The post and recess thus stabilize joint functions near and at full flexion by controlling the relative antero-posterior positions of the femur and preventing anterior translation.

If the knee should undergo a fairly large hyperextension (not shown, but see FIG. **7A**), say about 15°, the anterior part of the superior wall **16***a* of the femoral recess **16** will roll back into engagement with the anterior surface of the tibial post and prevent posterior dislocation of the femur.

We claim:

1. In a knee joint prosthesis having

a femoral component which includes a pair of laterally spaced-apart condylar portions, each of which has an external surface which is smoothly convexly curved antero-posteriorly to match generally the

lateral profile of an anatomical femoral condyle and smoothly convexly curved laterally throughout its antero-posterior extent, and a box-like intercondylar portion joining the condylar portions; and

a tibial component which includes a plate-like platform portion having on its superior surface a pair of laterally spaced-apart concavities, each of which is adapted to receive in nested relation one of the condylar portions of the femoral component, and a post extending superiorly from the platform surface intermediate the concavities for reception in the intercondylar portion of the femoral component;

the improvements wherein:

the intercondylar portion defines a recess opening inferiorly toward the tibial component and includes spaced-apart lateral walls, a superior wall which joins the lateral walls and has an inferior surface that is generally flat, lies generally parallel to a reference plane perpendicular to the nominal axis of the extended leg and intersects a patella portion of the femoral component at a location that is substantially above the platform portion of the tibial component and generally level with the top of the tibial post at full extension, and a cam follower portion at the posterior end of the superior wall having a transverse convexly curved follower surface; and

the tibial post has a posterior surface having a concavely curved cam portion adjacent the juncture between the post and the platform surface, the cam portion on the post being adapted to be ordinarily engaged by the follower surface on the intercondylar portion only after about 40° to 50° flexure of the leg and a tendancy of the femur to translate anteriorly relative to the tibia and to force the zones of contact between the femoral condylar surfaces of the femoral component and the concavities of the tibial component posteriorly as the degree of leg flexion increases.

2. A knee joint prosthesis according to claim 1 wherein the tibial post is generally triangular in lateral profile and includes a generally flat anterior surface lying obliquely at an acute angle to said reference plane, the anterior surface of the tibial post being engageable by an anterior part of the inferior surface of the superior wall of the intercondylar recess of the femoral component only upon hyper-extension of the leg and not otherwise.

3. A knee joint prosthesis according to claim 1 wherein an anterior portion of the inferior surface of the superior wall of the recess of the femoral component slopes at a small acute angle inferiorly and anteriorly thus to afford engagement with the anterior surface of the post of the tibial component upon, and only upon about 15° of hyper-extension of the leg.

4. A knee joint prosthesis according to claim 1 wherein the superior surface of the tibial component slopes inferiorly and posteriorly relative to the reference plane, thus to permit a high degree of flexion of the leg without interference between the anatomical femur and the posterior portion of the tibial component.

* * * * *

Exhibit C

United States Patent [19]
Whiteside

[11] **Patent Number: 4,467,801**
[45] **Date of Patent: Aug. 28, 1984**

[54] **METHOD AND APPARATUS FOR SHAPING A PROXIMAL TIBIAL SURFACE**

[75] Inventor: **Leo A. Whiteside**, Chesterfield, Mo.

[73] Assignee: **Wright Manufacturing Company**, Arlington, Tenn.

[21] Appl. No.: **473,464**

[22] Filed: **Mar. 9, 1983**

[51] **Int. Cl.**[3] **A61F 5/04**
[52] **U.S. Cl.** ..... **128/303 R**; 128/92 E; 128/305
[58] **Field of Search** ..... 128/92 H, 92 E, 92 EB, 128/92 EA, 92 BC, 92 CA, 92 C, 303 R, 304–305

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Primary Examiner—C. Fred Rosenbaum
Assistant Examiner—C. W. Shedd
Attorney, Agent, or Firm—Richard E. Rakoczy

[57] **ABSTRACT**

The present invention provides a method and apparatus for preparing the proximal surface of a tibia to receive a proximal tibial prosthesis employing a reamer/alignment guide which is used to internally locate the central long axis of the tibia and a plateau planar which cooperatively engages with a guide handle attached to the reamer/alignment guide to accomplish the shaping of the proximal tibial surface. The reamer/alignment guide has a rod portion extending into the interior of the tibial shaft whose central long axis corresponds with the central long axis of the tibia. The guide handle is concentric with that rod portion such that the plateau planar assumes the proper alignment with respect to the central long axis of the tibia such that the proximal tibial surface is shaped relative to that axis in a simple and accurate manner.

7 Claims, 11 Drawing Figures

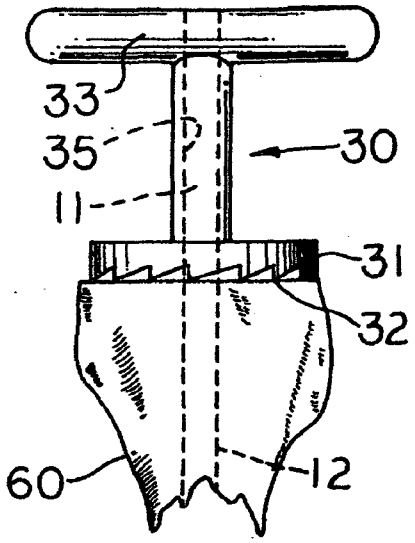


Fig. 1

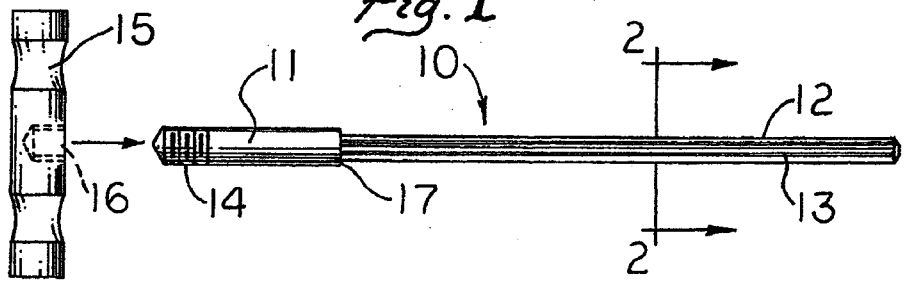


Fig. 2

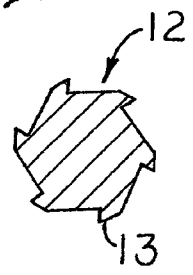


Fig. 3

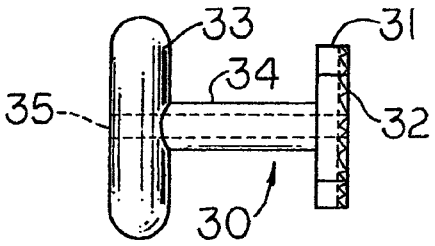


Fig. 4

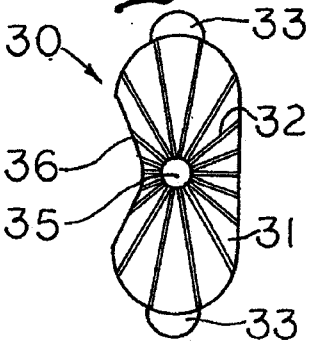


Fig. 5

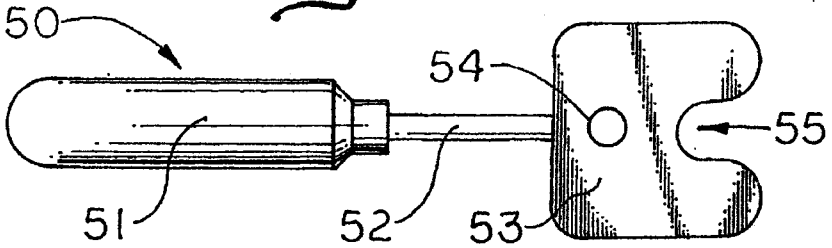


Fig. 6

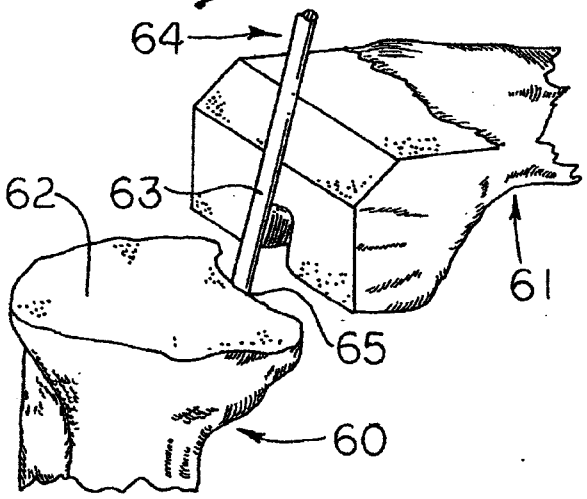


Fig. 9

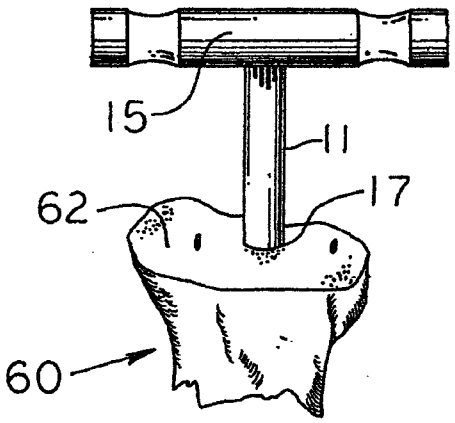


Fig. 7

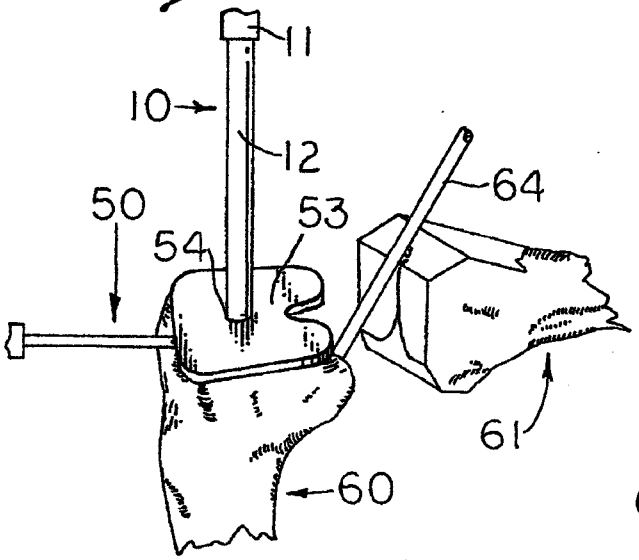


Fig. 10

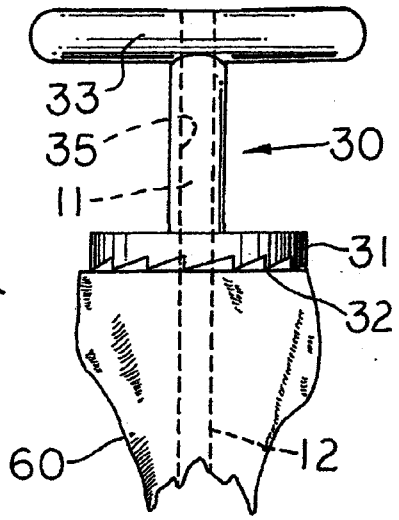


Fig. 11

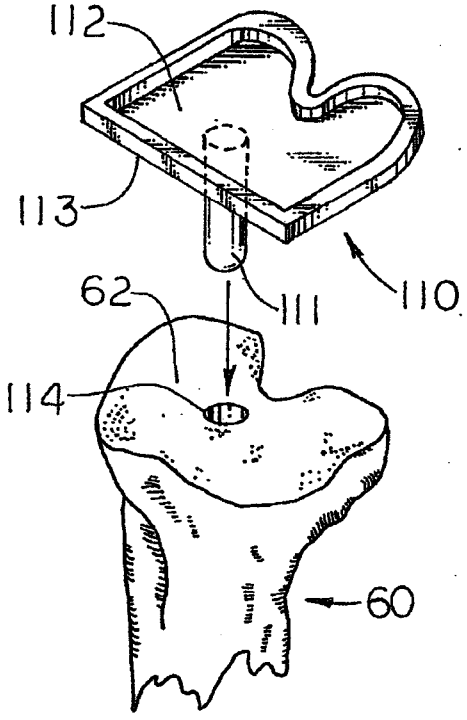
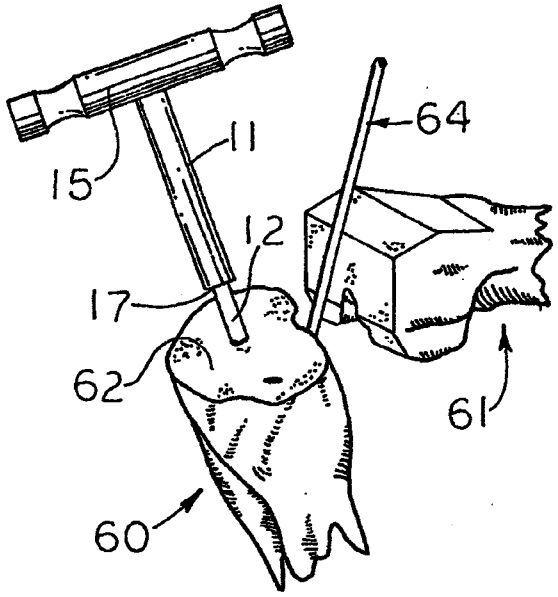


Fig. 8



METHOD AND APPARATUS FOR SHAPING A PROXIMAL TIBIAL SURFACE

BACKGROUND OF THE INVENTION

This invention relates to a method and apparatus for shaping the proximal surface of a human tibia to receive a proximal tibial knee prosthesis employing a reamer-/alignment guide in combination with a plateau planer instrument which cooperatively engages the guide. The planer instrument modifies the proximal tibial surface transversely with respect to the central long axis of the guide and the central long axis of the shaft of the tibia.

Various types of instruments and methods have been developed to enable a surgeon to affix a proximal tibial prosthesis to the human tibia. Such methods are generally employed in conjunction with the implantation of a total knee implant involving the implantation of both a distal femoral prosthesis and a proximal tibial prosthesis which cooperate with each other to replace a diseased or otherwise defective human knee and to restore a patient's ability to walk.

It is important that each prosthesis which is implanted be attached to the femur and tibia in such a manner that it approximates as closely as possible the natural portion of the knee which the prosthesis replaces. For example, if the proximal tibial prosthesis is not properly affixed with respect to the central long axis of the tibial shaft, an unnatural gait or other complications can result.

It is a common practice to use the long central axis of the femur as an alignment guide to determine the proper manner in which a distal femoral prosthesis is to be attached to the femur. The central long axis of the shaft of the tibia is then located and the proximal surface of the tibia is horizontally resected and prepared to receive a proximal tibial prosthesis which typically is chosen to lie in the plane of the transverse axis of the knee. If the tibial surface does not lie in the plane chosen, the implanted prosthesis may not properly align with the distal femoral prosthesis and complications can result.

One example of a method and apparatus for resecting the proximal tibial surface which employs external alignment guides situated outside of the flesh covering the femur and the tibia can be found in the "The HOWMEDICA ® Universal ™ Total Knee Instrument System", brochure no. H-2026-1 1/82 15M B (1980) from Howmedica, Inc., Orthopaedics Division, Rutherford, NJ 07070 which is hereby incorporated by reference. Another method which employs a tibial resection guide which is fixed to both the distal femoral surface and to the tibia by means of pins and employs an external alignment rod situated outside of the skin over the tibia is shown in a brochure entitled "New Jersey Tricompartmental Total Knee Replacement Surgical Procedure by Frederick F. Buechel, M.D.", 13 pages, issue date 1/1981, Form No. 1280-32, from DePuy Division, Boehringer Mannheim Corporation, Warsaw, Ind. 46580. Other examples of instruments which are intended to rest against the outside of the long axis of the tibia are the MULTI-RADIUS total knee tibial alignment guide (Catalog No. 1360-30) from Zimmer USA, Inc., Warsaw, Ind. 46580 and the Total Condylar Total Knee System tibial cutter (Catalog No. 6737-6-300) and HOWMEDICA ® KINEMATIC ™ Condylar Total Knee System tibial guide assembly (Catalog No. 6737-7-630), both of which are products of Howmedica, Inc., Orthopaedics, Division. Still another tibial alignment instrument in Catalog No. 1348-54 from Zimmer USA, Inc. which is inserted into the fixation holes for the femoral component of the GEO-PATELLA ™ /GEO-TIBIAL ™ total knee and employs an external guide which is aligned with the tibia to mark the points where the resection should be made.

External alignment instruments have a disadvantage in that the surgeon is relying upon visual and tactile means for positioning the alignment means since the patients's skin covers the major portion of the tibia and screens it from view. Locating the shaft of the tibia of an obese person or of a person having a deformity of the tibia which may somewhat alter its true central axis can present further difficulties.

SUMMARY OF THE INVENTION

There appears to be a need for a method of shaping the proximal surface of a tibia to receive a proximal tibial prosthesis which enables a surgeon to shape that surface as accurately as possible while using the central long axis of the shaft as a guide.

One object of the present invention is to provide a means by which the central long axis of the shaft of the tibia can be more accurately determined through the use of an instrument passing through the center of the shaft of the tibia.

It is another object of the present invention to provide a reamer/alignment guide upon which a plateau planer for the proximal surface of the tibia can be mounted such that the alignment of the abrading surface of the planer is always made relative to the central long axis of the shaft of the tibia.

It is yet another object of the present invention to provide a plateau to accomplish the shaping of the proximal tibial surface to obtain a much smoother and accurately planed surface than is typically obtained with an oscillating saw. That accurately planed, level surface is highly desirable when a proximal tibial prosthesis employing a cementless fixation means such as a porous ingrowth coating is to be affixed to the tibia.

It is still another object of the present invention to provide a method for overcoming the detrimental effects which deformities cause in locating the central long axis of the tibia and thereby enable a surgeon to more accurately shape the proximal surface of such a tibia to receive a proximal tibial prosthesis.

These and other objects of the present invention are provided by a method which comprises preparing the proximal tibial surface; determining the approximate location where the central long axis of the tibia (lying along the center of the interior of the tibial shaft) passes through the proximal tibial surface; advancing a reamer/alignment guide through that location for a sufficient distance along the interior of the tibial shaft to allow the central long axis of the tibia to correspond to that of the reamer/alignment guide; attaching a plateau planer to the handle of the reamer/alignment guide; modifying the proximal tibial surface using the plateau planer; trimming any remaining bone from the proximal tibial surface to obtain a smooth flat surface on which a tibial prosthesis can be affixed; and removing the reamer/alignment guide.

This invention also provides a reamer/alignment guide in combination with a plateau planer which cooperatively engages with the reamer/alignment guide and enables the proximal tibial surface to be shaped in a planer fashion transverse to the central long axis of the

tibia. The invention also provides a plateau planer having a planer abrading surface, a handle and a shaft connecting the two.

BRIEF DESCRIPTION OF THE DRAWINGS

The above and other objects, features and advantages of the present invention will become apparent to those skilled in the art upon an examination of the following description and drawings which are merely illustrative of the present invention.

In the Drawings

FIG. 1 is an exploded plan view of a preferred reamer/alignment guide and its handle.

FIG. 2 is a cross-section taken along section line 2—2 of FIG. 1.

FIG. 3 is a side view of a preferred plateau planer.

FIG. 4 is a view of FIG. 3 taken from below.

FIG. 5 is a plan view of a tibial reamer insertion guide.

FIG. 6 is a perspective view of the tibia and femur being separated.

FIG. 7 is a perspective view showing the marking of the approximate location for the entry of the reamer-/alignment guide.

FIG. 8 is a perspective view from the side showing the advancement of reamer/alignment guide into the tibial shaft.

FIG. 9 is a perspective view of the reamer/alignment guide fully advanced into the tibial shaft.

FIG. 10 is a frontal perspective view showing the plateau planer in place.

FIG. 11 is an exploded perspective view taken from the side showing placement of a proximal tibial prosthesis in the hole left by the reamer/alignment guide.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the Drawings, FIG. 1 depicts a preferred form of a reamer/alignment guide 10 which is a rod having a first portion 12 which is intended to enter the interior of the tubluar shaft of the tibia which is an interior region bounded by hard compact (cortical) bone. Portion 12 has a plurality of cutting ridges 13 situated about its circumference. Portion 12 has an outer diameter (including the cutting ridges) of such a dimension that it approximates the narrowest portion of the interior of the tibial shaft. FIG. 2 shows the portion 12 and the cutting ridges 13 in cross-section.

In the preferred embodiment shown, six cutting ridges are equidistantly situated about the circumference of portion 12. The remaining portion of reamer-/alignment guide 10 is preferably a smooth portion 11 of a slightly larger diameter than portion 12 which is intended to contact the proximal tibial surface and thereby indicate when the reamer is fully inserted within the interior of the tibial shaft as will be described infra. The end of portion 11 contains threads 14 or some other means by which opening 16 of handle 15 may be fitted over and secured to the end of portion 11 as a means to enable a twisting motion to be imparted to reamer/alignment guide 10 during use. In a preferred embodiment, portion 12 is 10" (254 mm) in length and 0.359" (9.12 mm) in outer diameter from the top at one cutting ridge to the ridge opposite it) and portion 11 is about 3.6" (91 mm) in length and 0.495" (12.6 mm) in outer diameter where the symbol " means inches and the symbol mm means millimeters. For use with a tibia having a significant degree of deformity, a reamer wherein portion 12 is 7" (178 mm) can be used.

Portion 11 also serves a second purpose as a guide handle for the hereinafter described plateau planer. Portion 11 (hereinafter —guide handle 11")is concentric with first portion 12 of guide 10 and when guide 10 is advanced a sufficient distance through the interior of the tibial shaft until portion 12 is aligned with the long central axis of the tibia, the long central axis of guide handle 11 also lies along the long central axis of the tibia. If it is desired, other instruments for the guiding of shaping instruments or for use in directly shaping the proximal tibial surface can also be attached to guide handle 11 such that shaping operations using such instruments can be carried out relative to the central long axis of the tibia.

FIG. 3 shows a plateau planer having a planar abrading surface 31 which, in the preferred embodiment shown, possesses a plurality of spaced cutting ridges 32 which are planar and are situated transverse to the central long axis of guide handle 11 (not shown). Guide handle 11 is inserted through passage 35 which is adapted to cooperatively engage handle 11 thereby enabling the plateau planer 30 to be freely rotated against the proximal tibial surface (not shown) about the central long axis of the guide handle 11 and thus rotated about the central long axis of the shaft of the tibia. Planar abrading surface 121 is rotated about the proximal tibial surface by imparting a twisting motion to handle 33 which is attached to abrading surface 121 by means of shaft 124. Passage 35 preferably has a 0.500" (12.7 mm) diameter when preferred guide handle 11 having a 0.495" (12.6 mm) outer diameter is employed.

FIG. 4 shows plateau planer 30 from below and more clearly shows the preferred configuration of cutting ridges 32 found on abrading surface 31 and their relationship to passage 35 and handle 33. Also shown is recessed area 36 in plateau planer 120 which is included to avoid trauma to anatomical members found about the intercondylar fossa of the proximal tibial surface.

The preferred configuration of the plateau planer is the one shown in FIGS. 3 and 4 wherein (a) handle 33 is situated above and parallel to planar abrading surface 31, (b) shaft 34 is transverse to both planar abrading surface 31 and to handle 33 and (c) passage 35 extends through the centers a planar abrading surface 31, shaft 24 and handle 33.

The above described reamer/alignment guide, plateau planer and components thereof are all preferably manufactured from a suitable surgical grade of stainless steel of the type commonly employed by those skilled in the art to construct surgical tools for use in contact with the body. The exact composition of the metal from which the guide, planer and components thereof are constructed forms no part of the present invention and other metals suitable for use within the body and for the intended uses of the guide, planer and the like may be used without altering the nature of the invention.

It should also be noted that another advantage of the present invention is that the above-described reamer-/alignment guide and plateau planer can be used in modifying the surface of either the right or the left proximal tibial surface.

Fig. 5 shows a proximal tibial surface reamer insertion guide 50 having handle 51 and guideplate 53 interconnected by means of arm 52. Guideplate 53 is of such a configuration that it is designed to approximate the outline of the superior proximal surface of the tibia and

to rest thereon such that when guideplate 53 is placed on that superior surface, the surface of guideplate 53 opposite handle 51 is lined up with the posterior aspects of the medial and lateral tibial condyles and recess 55 corresponds to the posterior intercondyloid fossa of the tibia. Hole 54 is of the same diameter as is portion 12 of guide 10 and is placed on guideplate 53 during its manufacture in a location which is such the the approximate central long axis of the tibia passes through hole 53. Since tibias differ in size, several guideplates of varying sizes may be provided and the one which most closely corresponds to the outline of the proximal tibial surface to be shaped is used. The exact center of hole 54 need not correspond exactly to that of the central long axis of the tibia since the reamer/alignment guide will adjust the entry point to correspond to that axis as will be described infra. Guide 50 can be manufactured from the same type of metals previously described for the reamer/alignment guide.

The manner in which the method of the present invention may be carried out will now be described. The proximal tibial surface is most often reshaped pursuant to the implantation of a total knee implant involving prostheses which are attached to the distal femoral surface and the proximal tibial surface. The present method and apparatus for shaping the proximal tibial surface described herein is advantageously and preferably employed in conjunction with the method and apparatus described in my copending U.S. patent application Ser. No. 473,465 entitled "Method and Apparatus For Shaping a Distal Femoral Surface" which is being filed concurrently herewith in the name of Leo Allen Whiteside (which application is hereby incorporated by reference). The method described in that patent application can be combined with that of the present invention to produce appropriately shaped distal femoral and proximal tibial surfaces to which the appropriate prostheses can be attached during total knee implantation surgery.

Preferably, the appropriate preoperative procedures of the type described in my copending patent application are followed.

Operatively, the usual surgical approach is made. After the anterior aspect of the knee is exposed, the knee is flexed to 100° so that the posterior curved surfaces of both femoral condyles can be visualized. Partial excision of the fatpad may be necessary. The preceding operative approach is not illustrated and for the purposes of clarity, soft tissue, ligaments and other nonessential elements have been eliminated from FIGS. 6–11.

Preferably, the distal femoral surface is shaped first in accordance with the procedure described in my aforementioned patent application if a total knee prosthesis is to be implanted. The details of that method are found in that patent application which is incorporated by reference and will not be repeated here. FIG. 6 shows distal femur 61 which was shaped in accordance with that method.

The shaping of the proximal tibial surface is begun by using an oscillating saw to resect a small amount of the superior proximal surface of the tibia to form an approximately planar surface 62 as is generally shown in FIG. 6. The surface 62 need not be absolutely planar because the purpose is to provide a relatively flat surface upon which the plateau planer will be placed to produce a planar surface as described infra. Care should be taken to remove as little bone as is appropriate. In varus knees with a depressed proximal medial tibial plateau, the hard cortical bone is left intact and the surface of the proximal lateral tibial plateau is removed with an oscillating saw. In valgus knees with a depressed proximal lateral tibial plateau, the lateral cortical weight bearing surface is left intact and the proximal medial tibial surface is removed with the oscillating saw. The anterior cruciate ligament and the posterior segments of the menisci (not shown) are removed from the upper tibial surface.

Referring again to FIG. 6, a lever type retractor 64 is inserted just lateral to the tibial attachment of the posterior cruciate ligament and the retractor 64 is placed in the intercondylar notch 63 of the right femur 61. The roughly flattened superior proximal surface 62 of right tibia 60 is levered forward to expose the entire superior proximal tibial surface 62.

Guideplate 53 of tibial reaming guide 50 is placed on surface 62 as shown in FIG. 7. The bottom of guideplate 53 may have small pins or some other means extending away from its lower surface (not shown) which engage surface 62 and hold guideplate 53 in place. The distal tip of portion 12 of reamer/alignment guide 10 is inserted into hole 54 and portion 12 is used to mark the location at which reamer/alignment guide 10 is to be advanced into the tibia 60 by turning guide 10 from side to side or by striking it with a mallet.

After marking the location for the entry of portion 12, guide 50 is removed and portion 12 of reamer/alignment guide 10 is advanced through surface 62 into the interior of the shaft of the tibia as shown in FIG. 8. Insertion of reamer/alignment guide 10 often requires alternate turning of guide 10 and striking of the handle 15 with a mallet. Guide handle 11 is of a slightly larger outer diameter than that of portion 12 and the boundary between the two is shown as surface 17.

FIG. 8 shows guide 10 advancing through surface 62 with the central long axis of portion 12 and handle 11 in a somewhat exaggerated fashion relative to the central long axis of the tibia 60. This illustrates one advantage of using the reamer/alignment guide of the present invention. At times, portion 12 will advance through the cancellous bone of the proximal tibial surface 62 as it is inserted. This occurs because the proximal surface of a tibia is not always aligned directly over the isthmus of a tibia and the location marked by hole 54 on guideplate 53 does not correspond to the central long axis of the tibia. As long as the reamer/alignment guide engages the isthmus of a tibia, it will advance through the interior of the tibial shaft through the softer interior that is bounded by the harder compact bone of the tibial shaft if a reasonable, but not excessive, amount of force is used to turn the handle 15 of guide 10 and advance it. As portion 12 follows the interior of the tibial shaft, it is brought into alignment with the central long axis of the tibia. Portion 12 also exerts a lateral reaming action on the proximal tibial surface 62 such that the entry point is moved laterally until the central axis of guide 10 extends through surface 62 at a location which corresponds to the central long axis of tibia 60. The passage left in surface 62 upon later removal of guide 10 can then be used as a point for the insertion of the retention stem of a proximal tibial prosthesis.

FIG. 9 shows guide 10 fully advanced into tibia 60 with surface 17 of handle 11 contacting proximal tibial surface 62.

Handle 15 is removed from guide handle 11 and plateau planer 30 is inserted over guide handle 11 with planar abrading surface 31 having planar cutting ridges 32 placed against surface 62 of tibia 60 as shown in FIG.

10. Plateau planer 30 cooperatively engages handle 11 and aligns with the central long axis of reamer/alignment guide 10 which is shown in outline form as first portion 12 and guide handle 11, the latter of which passes through passage 35 of planer 30. Proximal tibial surface 62 is shaped to a smooth, planar surface which is transverse to the central long axis of the tibia by grasping handle 33 and twisting it from side to side as planar abrading surface 31 is held against surface 62 of tibia 60.

This operation typically leaves hard cortical bone on either the medial or the lateral proximal tibial surfaces which may be removed with an oscillating saw. Occasionally it is necessary to use an oscillating saw to trim down the sclerotic proximal tibial surface in order to facilitate planing.

After a smooth, planar, proximal tibial surface is obtained, the reamer/alignment guide is removed. In some cases it may be necessary to remove a small ridge of bone from the periphery of the planed proximal tibial surface 62. The implantation of one of a number of well known proximal tibial prostheses can then proceed along with the attachment of an appropriate distal femoral prosthesis.

The plateau planer produces a much smoother and planar surface than is usually the case with an oscillating saw because such saws tend to ride over hard bone and cut into the softer areas on the tibial surface. The plateau planer cannot ride over the hard bone and results in a very level and accurately planed surface because the guide handle 11 holds planar abrading surface 31 in place. The resulting planar surface provides a firm mounting for a prosthesis and enables the maximum amount of proximal tibial surface to contact the surface of a proximal tibial prosthesis.

The passage 114 in tibia 60 which is left when portion 12 is removed corresponds to the central long axis of tibia 60 and, as shown in FIG. 11, provides a convenient location in which the stem 111 of a proximal tibial prosthesis 110 having upper surface 112 which articulates the distal femoral prosthesis and a lower surface 113 which rests against surface 62 of tibia 60. Depending upon the type of total knee implant chosen, it may be preferable to affix the distal femoral prosthesis prior to affixing the proximal tibial prosthesis, but the order of affixation should not affect the method of the present invention. After implantation of the prosthesis or prostheses in accordance with the usual surgical procedures, the wound is closed in the usual fashion.

Other modifications and variations of the method and apparatus of the present invention will become apparent to those skilled in the art from an examination of the above specification and drawings. Therefore, other variations of the present invention may be made which fall within the scope of the appended claims even though such variations were not specifically discussed above.

That which is claimed is:

1. A method of preparing a human tibia having a superior proximal surface and a central long axis defined by the interior of a tubular shaft of hard compact bone to receive a superior proximal tibial knee prosthesis, said method comprising the steps of

(A) resecting a small amount of the superior proximal surface of the tibia to form an approximately planar surface which is approximately transverse to the central long axis of the tibia,

(B) determining the approximate location on the superior proximal surface of the tibia which corresponds to the central long axis of the tibia,

(C) advancing a reamer/alignment guide through said superior proximal surface at said location along the interior of said tubular shaft of the tibia for a sufficient distance to enable the central long axis of said reamer/alignment guide to correspond with the central long axis of the tibia, said reamer/alignment guide comprising a rod having a first portion which is intended to enter the interior of said tubular shaft of the tibia which portion (1) is of an outside diameter approximating the narrowest portion of said interior and (2) has a plurality of cutting ridges situated about its circumference, the remaining portion of said rod acting as a guide handle which extends outwardly from said proximal surface and is concentric with the central long axis of said first portion, said handle further having a means thereon for imparting a twisting motion to said reamer/alignment guide,

(D) attaching a plateau planer to said guide handle, said planer comprising a planar abrading surface, a handle and a shaft connecting said planar abrading surface to said handle, said planer having a passage therethrough adapted to cooperatively engage said guide handle and to allow the planar abrading surface to be transversely rotated about the central long axis of said guide handle while it is in contact with the proximal surface of said tibia to flatten said proximal surface transversely with respect to the central long axis of the guide handle, said planar abrading surface containing a plurality of space cutting ridges which are planar and are situated transverse to the central long axis of said guide handle and further having a recessed area thereon to avoid trauma to anatomical members found about the intercondylar fossa of the proximal surface of the tibia,

(E) modifying said proximal surface of the tibia through the use of said planer until said surface is smooth, planar and transverse to the central long axis of said guide handle,

(F) trimming any remaining bone from the proximal surface of the tibia to present a smooth, flat surface on which a proximal tibial prosthesis can be affixed, and

(G) removing the reamer/alignment guide.

2. The method as claimed in claim 1 wherein in step (C), said guide handle has a smooth outer surface and has an outer diameter which is larger than that of said first portion.

3. The method as claimed in claim 1 wherein in step (D), the handle of said planer is situated above and parallel to said planar abrading surface, said shaft is transverse to both the planar abrading surface and to the handle, and said passage extends through the center of said planer abrading surface, said shaft and said handle.

4. As an article of manufacture, a proximal tibial surface cutting guide comprising the combination of

(A) a reamer/alignment guide comprising a rod having a first portion adapted to enter the interior of the tubular shaft of a tibia in such a manner that the central long axis of said first rod portion corresponds to the central long axis of the tibia, said first rod portion (1) being of an outside diameter approximating the narrowest portion of said interior

and (2) having a plurality of cutting ridges situated about its cicumference, the remaining portion of said rod being a guide handle which is concentric with the central long axis of said first portion and further has a means thereon for imparting a twisting motion to said reamer alignment guide, with

(B) a plateau planer comprising a planar abrading surface, a handle and a shaft connecting said planar abrading surface to said handle, said planer having a passage therethrough adapted to cooperatively engage said guide handle and to allow the planar abrading surface to be transversely rotated about the central long axis of said guide handle while it is in contact with the proximal surface of said tibia to flatten said proximal surface transversely with respect to the central long axis of the guide handle, said planar abrading surface containing a plurality of spaced cutting ridges which are planar and are situated transverse to the central long axis of said guide handle and further having a recessed area thereon to avoid trauma to anatomical members found about the intercondylar fossa of the proximal surface of the tibia.

5. The article as claimed in claim 4 wherein in (B), the handle of said planer is situated above and parallel to said planar abrading surface, said shaft is transverse to both the planar abrading surface and to the handle and said passage extends through the center of said planar abrading surface, said shaft and said handle.

6. As an article of manufacture, a plateau planer for modifying the proximal surface of a human tibia comprising a planar abrading surface, a handle and a shaft connecting said planar abrading surface to said handle, said planer havig a passage therethrough adapted to cooperatively engage a guide handle of a tibial alignment guide and to allow the planar abrading surface to be transversely rotated about the central long axis of said guide handle while it is in contact with the proximal surface of said tibia to flatten said proximal surface transversely with respect to the central long axis of the guide handle, said alignment guide being adapted to pass through the central long axis of a tibia wherein said guide handle is situated on said alignment guide in such a manner that said central long axis of the tibia corresponds with the central long axis of the guide handle, said planar abrading surface containing a plurality of spaced cutting ridges which are planar and are situated transverse to the central long axis of said guide handle and further having a recessed area thereon to avoid trauma to anatomical members found about the intercondylar fossa of the proximal surface of the tibia.

7. The article as claimed in claim 6 wherein the handle of said planer is situated above and parallel to said planar abrading surface, said shaft is transverse to both the planar abrading surface and to the handle and said passage extends through the center of said planar abrading surface, said shaft and said handle.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 4,467,801

DATED : August 28, 1984

INVENTOR(S) : Leo A. Whiteside

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In column 2, line 34, "plateau to" should read -- plateau planer to --.

In column 3, line 42, "tubluar" should read -- tubular --.

In column 3, line 65, "it)" should read -- it --.

In column 4, line 46, "a planar" should read -- of planar --.

In column 4, line 47, "24" should read -- 34 --.

In column 5, line 8, "the the approximate" should read --that the approximate --.

In column 10, line 5, "havig" should read -- having --.

Signed and Sealed this

Fourteenth Day of October, 1986

[SEAL]

Attest:

Attesting Officer

DONALD J. QUIGG

Commissioner of Patents and Trademarks

Exhibit D

United States Patent [19]

Whiteside

[11] **Patent Number: 4,474,177**

[45] **Date of Patent: Oct. 2, 1984**

[54] **METHOD AND APPARATUS FOR SHAPING A DISTAL FEMORAL SURFACE**

[75] Inventor: **Leo A. Whiteside**, Chesterfield, Mo.

[73] Assignee: **Wright Manufacturing Company**, Arlington, Tenn.

[21] Appl. No.: **473,465**

[22] Filed: **Mar. 9, 1983**

[51] **Int. Cl.**³ **A61F 5/04**

[52] **U.S. Cl.** ..... **128/303 R**; 128/92 R; 128/92 E

[58] **Field of Search** ..... 128/92 H, 92 C, 92 CA, 128/92 BC, 92 EA, 92 EB, 92 E, 303 R

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Primary Examiner—C. Fred Rosenbaum

Assistant Examiner—C. W. Shedd

Attorney, Agent, or Firm—Richard E. Rakoczy

[57] **ABSTRACT**

The present invention provides a method and apparatus for preparing the distal surface of a femur to receive a distal femoral prosthesis employing an intramedullary reamer which is used to internally locate the central long axis of the femur, an intramedullary alignment guide which is inserted into the space left in the intramedullary canal upon removal of the reamer and at least one femoral surface modifying instrument which cooperatively engages with a guide handle attached to the intramedullary alignment guide to accomplish the shaping of the distal femoral surface. The intramedullary alignment guide has a rod portion extending into the femoral intramedullary canal whose central long axis corresponds with the central long axis of the femur. The guide handle is attached to that rod portion at a preselected angle such that the shaping instruments fixed thereto assume the proper alignment with respect to the central long axis of the femur such that the distal femoral surface is shaped relative to that axis in a simple and accurate manner.

10 Claims, 23 Drawing Figures

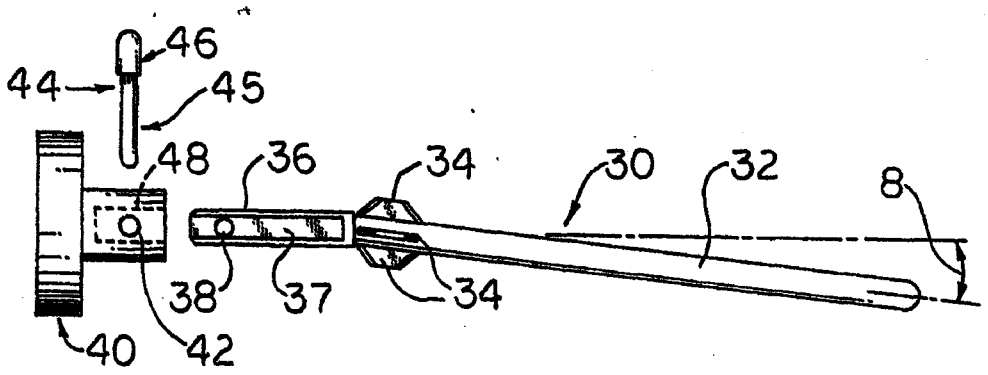


Fig. 1

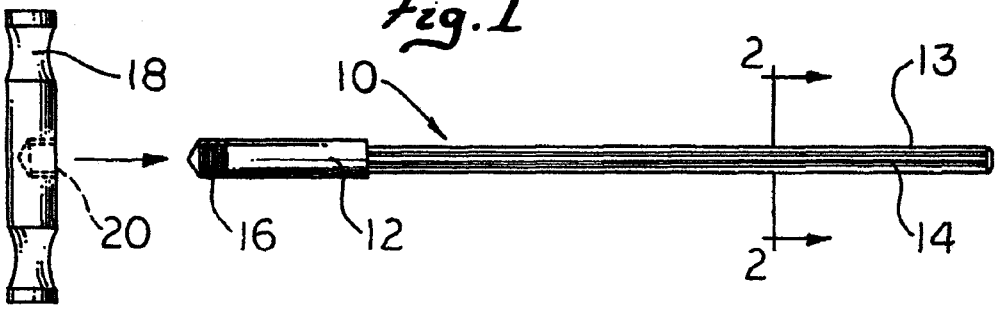


Fig 3

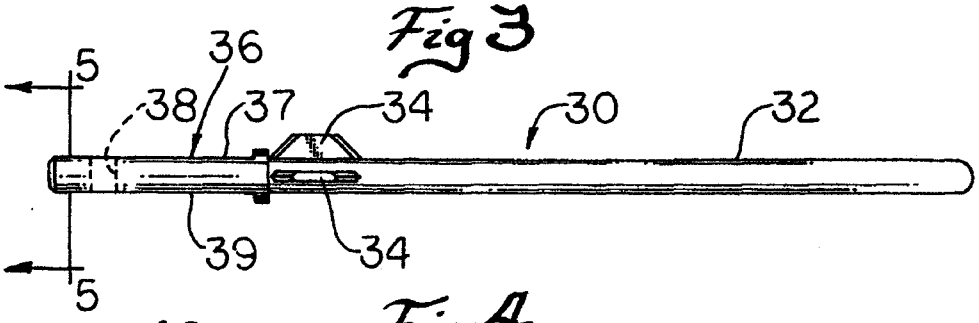


Fig. 4

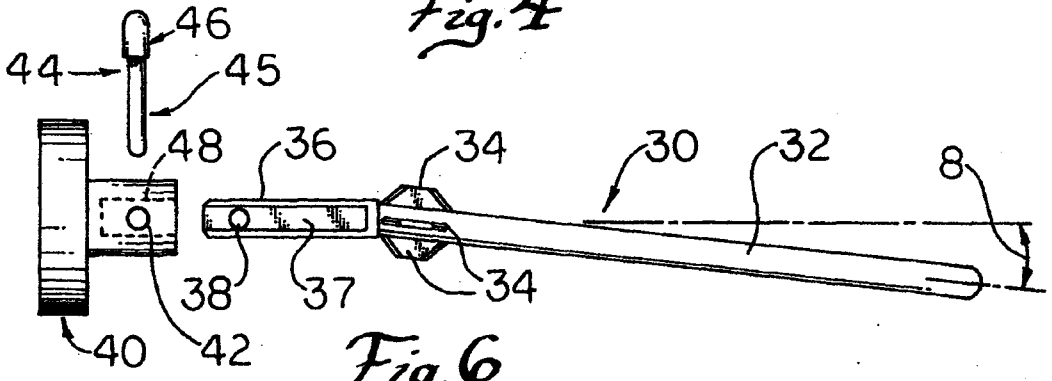


Fig. 6

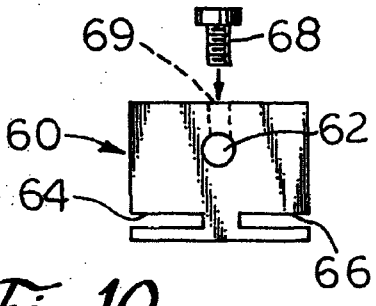


Fig. 2

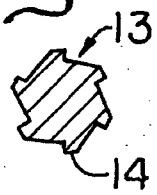
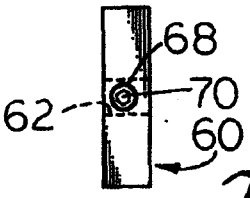


Fig. 7



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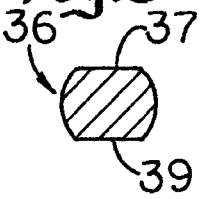
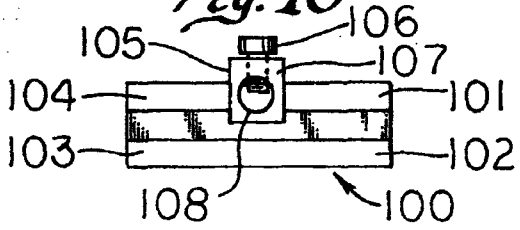


Fig. 10



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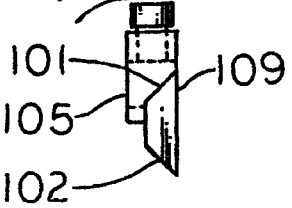

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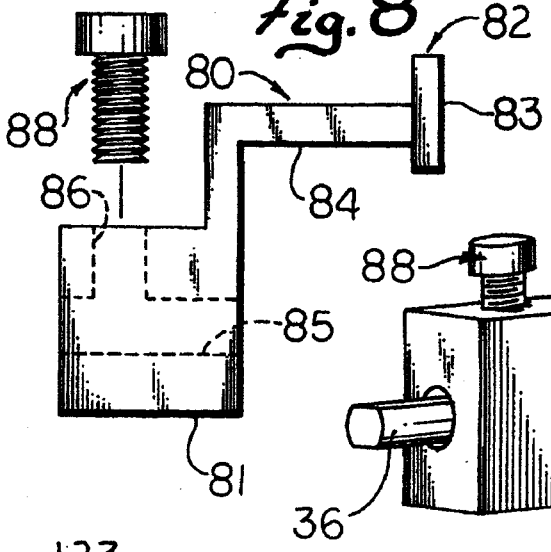

Fig. 9

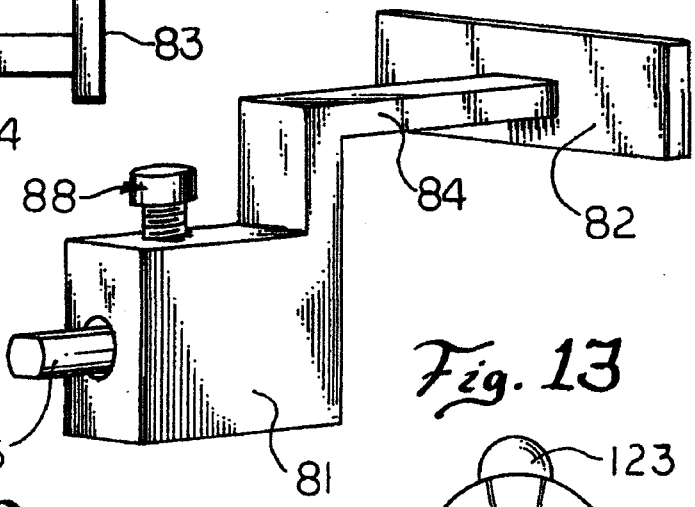

Fig. 12

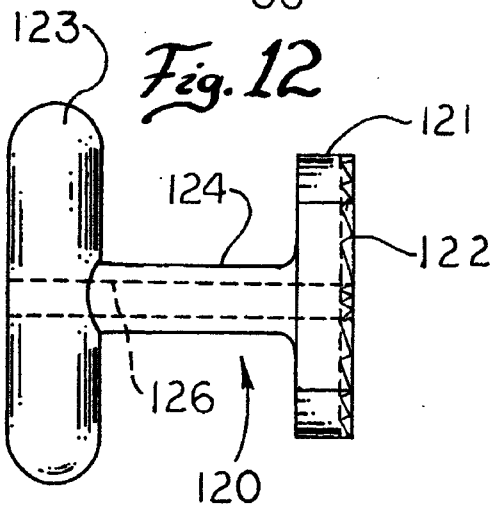

Fig. 13

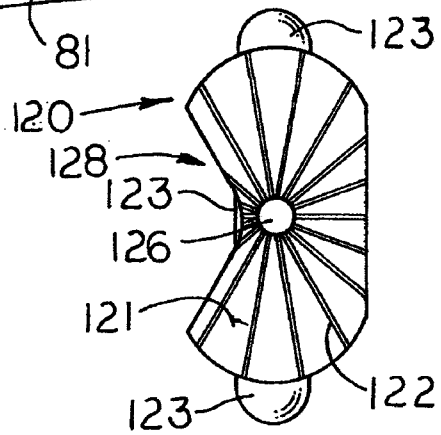

Fig. 17

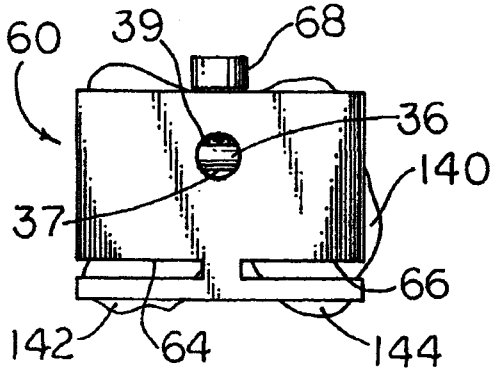

Fig. 14